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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,791	09/06/2006	Jean-Luc Gala	DECLE59.013APC	1433

20995 7590 02/19/2009  
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EXAMINER
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MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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02/19/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,791	<b>Applicant(s)</b> GALA ET AL.	
	<b>Examiner</b> Carla Myers	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **Election/Restrictions**

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, drawn to methods for identifying gram positive and gram negative microorganisms.

Group II, claims 9-19, drawn to primers and probes for identifying gram positive and gram negative microorganisms.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the claimed inventions do not share a linking technical feature because the technical feature of invention I was known in the art at the time the invention was made. In particular, Carroll (Journal of Clinical Microbiology. 2000. 38: 1753-1757; cited in the IDS) teaches methods for discriminating between gram-positive and gram-negative bacteria comprising detecting the presence of a conserved DNA sequence (marker) of gram-

Art Unit: 1634

positive bacteria and the presence of a conserved DNA sequence (marker) of gram-negative bacteria (see abstract and page 1754). Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

### **3. Further restriction requirement applicable to invention I**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- the gram-positive sequences of Spy0160, Spy1372, SpyM3 0902, SpyM3\_0903, and Spy152; and
- the gram-negative sequences of Ecs0036, HI1576, EG10839, EGI1396, and HI0019.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable.

That is, applicant is required to elect one gram-positive sequence and one gram-negative sequence, or one combination of gram-positive and gram-negative sequences

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

Art Unit: 1634

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 4 and 5 encompass the species of the Spy0160, Spy1372, SpyM3 0902, SpyM3\_0903, and Spy152 molecular marker sequences;

Claims 6 and 7 encompass the species of the Ecs0036, HI1576, EG10839, EGI1396, and HI0019 molecular marker sequences

The following claim(s) are generic: claims 1-3 and 8

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited genes differ from one another with respect to their nucleotide structure, their specificity of hybridization and their functional activity. The genes thereby have a different chemical structure and different biological activity. Thus, the claimed genes do not have both a "common property or activity" and a common structure, essential to that property or activity, as would be required to show that the inventions are "of a similar nature."

#### **4. Further restriction requirement applicable to invention I**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Art Unit: 1634

- the gram-positive sequences of SEQ ID NOs 1-62, 64-107, 109-111, 117-129, 137, 145-148, 150-193, 233-237, 240-241,255, 326-395, 397-399, and 404-425; and
- the gram-negative sequences of SEQ ID NOs 63, 108, 112-116, 130-136, 138-144, 194-232, 238-239, 242-254, 256-325, 396, 400-403, and 426-461.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable.

That is, applicant is required to elect one gram-positive sequence and one gram-negative sequence, or one combination of gram-positive and gram-negative sequences. This election must be consistent with the election of the molecular marker sequence, as set forth in paragraph 3 above.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 5 encompasses the species of the SEQ ID NOs 1-62, 64-107, 109-111, 117-129, 137, 145-148, 150-193, 233-237, 240-241,255, 326-395, 397-399, and 404-425;

Art Unit: 1634

Claim 7 encompasses the species of SEQ ID NOs 63, 108, 112-116, 130-136, 138-144, 194-232, 238-239, 242-254, 256-325, 396, 400-403, and 426-461.

The following claim(s) are generic: claims 1-4, 6 and 8

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited genes differ from one another with respect to their nucleotide structure, their specificity of hybridization and their functional activity. The genes thereby have a different chemical structure and different biological activity. Thus, the claimed genes do not have both a "common property or activity" and a common structure, essential to that property or activity, as would be required to show that the inventions are "of a similar nature."

#### **5. Further restriction requirement applicable to invention II**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- the gram-positive sequences of Spy0160, Spy1372, SpyM3 0902  
SpyM3\_0903, Spy152; SEQ ID NOs 1-62, 64-107, 109-111, 117-129,  
137, 145-148, 150-193, 233-237, 240-241, 255, 326-395, 397-399, and  
404-425; and
- the gram-negative sequences of Ecs0036, HI1576, EG10839, EGI1396,  
and HI0019, and SEQ ID NOs 63, 108, 112-116, 130-136, 138-144, 194-  
232, 238-239, 242-254, 256-325, 396, 400-403, and 426-461.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable.

That is, applicant is required to elect one gram-positive primer pair and/or probe sequence and one gram-negative primer pair and/or probe sequence, or one combination of said sequences. The election of the primer pairs and probes must be consistent with one another. For example, if Applicant elects primer pairs for amplifying Spy0160 sequences, then if Applicant elects a probe, the elected probe must also be directed to Spy0160 sequences.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 9-19 encompass the species listed above.  
No claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited genes differ from one another with respect to their nucleotide structure, their specificity of hybridization and their functional activity. The genes thereby have a different chemical



Art Unit: 1634

structure and different biological activity. Thus, the claimed genes do not have both a "common property or activity" and a common structure, essential to that property or activity, as would be required to show that the inventions are "of a similar nature."

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-

Art Unit: 1634

0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/  
Primary Examiner, Art Unit 1634